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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,774	07/25/2001	Manaud Pierre Frederic De Raspide	PC10915A	5154

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/18/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,774

Applicant(s)

DE RASPIDE ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Response, received by the Office April 4, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 15-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 436 370 to Noda *et al.* in view of WO 00/32589 to Dallman *et al.*.

Noda *et al.* disclose a controlled release pharmaceutical preparation comprising a core containing a pharmaceutically active substance and a coating film formed on the surface of the core by aqueous coating of a water insoluble and slightly water permeable acrylic polymer containing a trimethylammonium-ethyl group. Noda *et al.* teach that the formulation of their invention can inhibit the dissolution and release of the pharmaceutically active substance for a fixed period of time and can rapidly release the active substance after the initiation of dissolving and releasing thereof (c 2, 1 1-5). This release pattern fits the description of sigmoidal release. Examples of the coating composition to be used is a combination of Eudragit RL and Eudragit RS (c 2, 1 50 – c 3, 1 8). Noda *et al.* teach that the core to be coated may be granules, having an average particle size of about 300 microns to 2000 microns (c 3, 1 20-25). Noda *et al.* also teach that the core can incorporate other conventional additives, such as excipients (lactose), binding

Art Unit: 1615

agents (PEG and starches), lubricants and the like (c 3, l 45-60). The reference also teaches that the coating composition may include further excipients such as plasticizers (triethyl citrate) and agglomeration inhibitors (titanium dioxide) (c 5, l 18-34). Noda *et al.* also teach two different methods for forming the core. The first method involves mixing the active together with the excipients to form a granules. Alternatively, the active agent and excipients can be coated onto an inert core to form the core (c 4, l 18-42). Lastly, Noda *et al.* teach that their invention can be used with any active agent which can be administered orally (c 3, l 26-40) and that the composition can be administered as such, or in the form of capsules filled with the granules (c 9, l 15-19).

Noda *et al.* does not specifically teach eletriptan as the active agent to be used in the formulation, nor do they teach that eletriptan is useful in the treatment of migraines.

Dallman *et al.* discussed dosage suitable forms comprising eletriptan hydrobromide monohydrate. Dallman *et al.* teach that the active agent can be administered orally, in the form of tablets (p 4, l 18-19). Dallman *et al.* also teach that the active agent is useful in the treatment of migraines.

It is the position of the examiner that one of ordinary skill in the art would have been motivated to use eletriptan in the formulation described by Noda. Noda *et al.* teach a new type of formulation, which has a particular release pattern, and which is useful for any active which can be administered orally. Dallman *et al.* teach that eletriptan can be administered orally and is useful in treating migraines. Therefore, one of ordinary skill in the art would expect a successful pharmaceutical formulation comprising eletriptan cores with an outer coating, thereby achieving the initial delay of release of the later rapid release of the active agent. Therefore,

Art Unit: 1615

this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that Noda *et al.* teach away from the claims which do not recite an organic acid in the core. The examiner respectfully disagrees with this argument, as the instant claims are written with open language, thereby not excluding the presence of an organic acid. Applicant further argues that Noda *et al.* do not specifically teach eletriptan as the active agent. This is acknowledged by the Examiner in the rejection, and addressed by incorporating the secondary reference. For these reasons, the above rejection is maintained.

Claims 1, 2, 4-9, 15, 17, 18, 20-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over "An Organix Acid Induced Sigmoidal Release System for Oral Controlled Release Preparations" by Narisawa *et al.* in view of Dallman *et al.*

Narisawa *et al.* disclose that a sigmoidal release system was developed in order to achieve a time controlled or site specific drug delivery in the GI tract. Sigmoidal release achieves a prolonged lag time followed by rapid release. Narisawa *et al.* teach that the formulation is prepared by making uncoated beads, comprising a mixture of the drug and excipients, and spraying this composition onto an inert non-pareil bead. The beads are then coated by spraying with a mixture of Eudragit RS, talc, triethyl citrate and water. The beads are approx. 1100 microns and the coating is about 90 microns.

Art Unit: 1615

Narisawa *et al.* do not teach the use of eletriptan specifically in the formulation, nor do they teach the use of eletriptan for the treatment of migraines.

Dallman *et al.* discussed dosage suitable forms comprising eletriptan hydrobromide monohydrate. Dallman *et al.* teach that the active agent can be administered orally, in the form of tablets (p 4, l 18-19). Dallman *et al.* also teach that the active agent is useful in the treatment of migraines.

It is the position of the examiner that one of ordinary skill in the art would have been motivated to use eletriptan in the formulation described by Narisawa *et al.*. Narisawa *et al.* teach a new type of formulation, which has a particular release pattern, and which is useful for any active which can be administered orally. Dallman *et al.* teach that eletriptan can be administered orally and is useful in treating migraines. Therefore, one of ordinary skill in the art would expect a successful pharmaceutical formulation comprising eletriptan cores with an outer coating, thereby achieving the initial delay of release of the later rapid release of the active agent. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant's arguments regarding this rejection are the same as those discussed earlier. Therefore, no further comment is deemed necessary.

Art Unit: 1615

Claims 13 and 14 are rejected under USC 103(a) as being unpatentable over Noda *et al.* in view of Dallman OR Narisawa *et al.* in view of Dallmann, both discussed above, further in view of US Patent 5,411,745 to Oshlack *et al.*

Both of the rejections discussed above teach a successful controlled release composition comprising a core and an acrylic coating to affect sustained release. Neither of the above rejections discuss the use of a protective coating between the core and the water insoluble permeable coating.

Oshlack *et al.* disclose an oral dosage form of morphine. However, this reference is relied upon for the teaching at page 15, lines 49-55, where it teaches that hydroxypropylmethyl cellulose can be used as a protective coating between cores and sustained release acrylic polymers. Oshlack *et al.* teach that this HPMC layer enhances stability of the composition. It is the position of the examiner that one of ordinary skill in the art would have been motivated to include a protective layer between the drug core and the outer permeable layer of the compositions discussed above. This motivation lies in the teaching of Oshlack *et al.* that a protective coating enhances the stability of the formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner/ AU 1615
June 13, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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